UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

1M

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/189,543	11/10/98	CHEE	A-66828-1/D.T

M

EXAMINER

MARSCHEL, A

ART UNIT	PAPER NUMBER
1631	14

DATE MAILED: 05/02/00

HM12/0502
FLEHR HOHBACH TEST ALBRITTON AND HERBERT
SUITE 3400
FOUR EMBARCADERO CENTER
SAN FRANCISCO CA 94111-4187

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File A-66828-1 Atty RMS, DCF
Due Date 8/2/2000
Type Final O.A. Refs —

3 mo 8.2.00
1 ext 9.2.00
2 ext 10.2.00
Drop Dead 11.2.00

PTO-90C (Rev. 2/95)

2 - Mail Copy

Offic Action Summary

Application No.	Applicant(s)
09/189,543	Chee et al.
Examiner	**Group Art Unit**
Ardin Marsch I	1631

[X] Responsive to communication(s) filed on *Feb 14, 2000*

[X] This action is **FINAL.**

[ ] Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

[X] Claim(s) *1-16* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

[ ] Claim(s) _____ is/are allowed.

[X] Claim(s) *1-16* is/are rejected.

[ ] Claim(s) _____ is/are objected to.

[ ] Claims _____ are subject to restriction or election requirement.

Application Papers

[ ] See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

[ ] The drawing(s) filed on _____ is/are objected to by the Examiner.

[ ] The proposed drawing correction, filed on _____ is [ ] approved [ ] disapproved.

[ ] The specification is objected to by the Examiner.

[ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

[ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

[ ] All [ ] Some* [X] None of the CERTIFIED copies of the priority documents have been

[ ] received.

[ ] received in Application No. (Series Code/Serial Number) _____.

[ ] received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

[ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

[ ] Notice of References Cited, PTO-892

[X] Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ *(4 sheets)*

[ ] Interview Summary, PTO-413

[ ] Notice of Draftsperson's Patent Drawing Review, PTO-948

[ ] Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Applicants' arguments, filed 2/14/00, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-16 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Consideration of the citations pointed to by applicants revealed that the limitation of discrete or individual sites on the substrate for microsphere attachment is separate from random distribution of microspheres. Citing these both as limitations in the same claims is NEW MATTER. For example, in the instant specification at page 9, line 30, through page 10, line 17, the patterning of sites, for example discrete sites, is an alternative to a random distribution and not practiced at the same time. See specifically page 10, line 7, where the alternative is given by the word "or" in said line. This

rejection is necessitated by amendment.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-16 are rejected under 35 U.S.C. § 102(b) and (e) as being clearly anticipated by Ekins et al.(P/N 5,516,635).

This rejection is maintained and reiterated from the previous office action, mailed 9/7/99, and as necessitated by amendment due to the newly added claims as discussed below. This rejection is maintained partly due to anticipation of removal of the above noted NEW MATTER thus leaving the claims rejected as before. Applicants also argue that Ekins et al. fails to teach a bioactive agent and an identifier. In response the binding of the microspheres is clearly via a bioactive agent such as an antibody. Secondly, the different markers such as multiple fluorescent labels decode target binding as an identifier. Applicants also argue that a single label is utilized in Ekins et

al. in contrast to multiple markers in the instant invention. In response Ekins et al. at column 4, lines 57-62, Ekins et al. specifically cites the use of multiple different dyes. Applicants further argue that non-optical signatures are required in instant claims 2, 6, and 13 contrary to the reference. In response, Ekins et al. includes enzymatic labels on the microspheres as given in column 4, lines 10-12, which are not optical labels but rather non-optical labels that are visualized via enzymatic reaction as a second step. It is noted that microtitre wells are tilized in Ekins et al. at column 13, lines 29-33, as also required in instant claims 15 and 16. This pointing to column 13 is necessitated by amendment.

Can we propose add limitation to, Patent cost

It is acknowledged that the following applications have been considered: 09/344,526; 60/090,473; 09/287,573; 08/944,850; 09/315,584; 09/256,943; 60/113,968; 09/151,877; 08/818,199; 08/851,203

No claim is allowed.

Applicants' amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED

STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technical Center receptionist whose telephone number is (703) 308-0196.

April 28, 2000

Ardin H. Marschel

ARDIN H. MARSCHEL
PRIMARY EXAMINER

APPENDIX- CURRENTLY PENDING CLAIMS

1. (Amended) An array composition comprising:

a) a substrate with a surface comprising discrete sites; and

b) a population of microspheres comprising at least a first and a second subpopulation, wherein each subpopulation comprises:

i) a bioactive agent; and

ii) an identifier binding ligand that will bind a decoder binding ligand such that the identification of the bioactive agent can be elucidated;

wherein said microspheres are randomly distributed on said surface.

2. (Amended) An array composition comprising:

a) a substrate with a surface comprising discrete sites; and

b) a population of microspheres comprising at least a first and a second subpopulation, wherein each subpopulation comprises a bioactive agent and does not comprise an optical signature, wherein said microspheres are randomly distributed on said surface.

3. A composition according to claim 1 or 2 further comprising at least one decoder binding ligand.

4. A composition according to claim 1 or 2 wherein said bioactive agents are nucleic acids.

5. A composition according to claim 1 or 2 wherein said bioactive agents are proteins.

6. (Amended) A method of making a composition comprising:

a) forming a surface comprising individual sites on a substrate;

b) randomly distributing microspheres on said surface such that said individual sites

contain microspheres, wherein said microspheres comprise at least a first and a second subpopulation each comprising a bioactive agent and do not comprise an optical signature.

7. (Amended) A method of making a composition comprising:

a) forming a surface comprising individual sites on a substrate;

b) randomly distributing microspheres on said surface such that said individual sites contain microspheres, wherein said microspheres comprise at least a first and a second subpopulations each comprising:

i) a bioactive agent; and

ii) an identifier binding ligand that will bind a decoder binding ligand such that the identification of the bioactive agent can be elucidated.

8. (Amended) A method of decoding an array composition comprising:

a) providing an array composition comprising:

i) a substrate with a surface comprising discrete sites; and

ii) a population of microspheres comprising at least a first and a second subpopulation, wherein each subpopulation comprises a bioactive agent;

wherein said microspheres are randomly distributed on said surface;

b) adding a plurality of decoding binding ligands to said array composition to identify the location of at least a plurality of the bioactive agents.

9. A method according to claim 8 wherein at least one subpopulation of microspheres comprises an identifier binding ligand to which a decoding binding ligand can bind.

10. A method according to claim 8 wherein said decoding binding ligands bind to said bioactive agents.

11. A method according to claim 8 wherein said decoding binding ligands are labeled.

12. A method according to claim 8 wherein the location of each subpopulation is determined.

13. (Amended) A method of determining the presence of a target analyte in a sample comprising:

a) contacting said sample with a composition comprising:

i) a substrate with a surface comprising discrete sites; and

ii) a population of microspheres comprising at least a first and a second subpopulation each comprising a bioactive agent and do not comprise an optical signature;

wherein said microspheres are randomly distributed on said surface such that said discrete sites contain microspheres; and

b) determining the presence or absence of said target analyte.

14. (Amended) A method of determining the presence of a target analyte in a sample comprising:

a) contacting said sample with a composition comprising:

i) a substrate with a surface comprising discrete sites; and

ii) a population of microspheres comprising at least a first and a second subpopulation each comprising:

1) a bioactive agent; and

2) an identifier binding ligand that will bind a decoder binding ligand such that the identification of the bioactive agent can be elucidated;

wherein said microspheres are randomly distributed on said surface such that said discrete sites contain microspheres; and

b) determining the presence or absence of said target analyte.

Please add the following new claims:

- -15. The composition according to claim 1 or claim 2, wherein said discrete sites are wells.

16. The method according to claim 6, claim 7, claim 8, claim 13 or claim 14, wherein said discrete sites are wells.- -.